

### **REMARKS**

Claim 2 has been canceled without prejudice. Claims 1, 4, 7, and 8-10 have been amended for greater clarity. New claim 33 has been added which depends from claim 4. Support for the amendments and new claim 33 is found throughout the specification. No new matter has been introduced and no new issues have been raised.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

#### **Claim Objections**

With regard to the formality objection, claim 1 has been amended to correct the typographic error in the recitation of "with a" and to add the symbol "°" for the temperatures. Applicant requests that the objections be withdrawn in light of the amendment.

#### **Claim Rejections under 35 U.S.C. § 101**

The Examiner alleges that claims 1-2, 4-10, and 12-15 read on the organism per se which is found in nature. To expedite prosecution, Applicants have amended independent claim 1 to recite "a biologically pure culture" as suggested by the Examiner, thereby obviating the rejection. Support for such claim amendments can be found throughout the specification (e.g., page 2, lines 26-28). Reconsideration and withdrawal of the rejection are respectfully requested.

#### **Claim Rejections under 35 USC § 112, First Paragraph**

With respect to the written description rejection, the Examiner asserts that "[i]t is not clear if the written description is sufficiently repeatable to avoid the need of for a deposit. Further, it is unclear if the starting materials were readily available to the public at the time of invention." Office Action, page 3, lines 3-5.

In response, Applicants submit that a sample of the claimed bacterial strain (*Lactobacillus fermentum* VRI003) was deposited at the International Depositary Authority on August 27, 2002,

with the Accession Number NM02/31074, under the terms of the Budapest Treaty. Applicants enclose herewith, as **Exhibit A**, a copy of the Deposit Receipt issued by the International Depositary Authority. As noted by the Examiner at page 4 of the Office Action, the making of such a deposit under the terms of the Budapest Treaty obviates this rejection. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim Rejections under 35 USC § 112, Second Paragraph

Claims 1-2 and 4-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. To expedite prosecution, Applicants have amended certain claims. Such amendments are not made in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope.

a. Applicants have amended claim 1 by adding the symbol ( $^{\circ}$ ) for degrees regarding temperatures. Regarding the recitations of “log 3” and “log 5,” Applicants submit that such recitations are well known and routinely used in microbiology to describe the growth characteristics of a bacterial culture, and the concentration of a bacterial culture (for example in “colony forming units” or “cfu” as used in part (f) of claim 1). As such, one of skill in the art would readily know that the terminology “log 3” refers to a value of approximately  $10^3$ , and similarly the terminology “log 5” refers to a value of approximately  $10^5$ .

b. Applicants contend that the term “stable” in claim 1(e) is described in detail in the specification such that one of skill in the art would know the metes and bounds of this term. For example, at page 6, lines 23-24, the term “stable” is defined as including “within its scope a loss of viability of up to 25% per six month’s storage at 25  $^{\circ}$ C”. Nevertheless, to expedite prosecution, Applicants have amended claim 1(e) to clarify the subject matter.

c. Regarding the recitation in claim 1(f), Applicants contend that the specification describes the connection between adhesion and inhibition of pathogens (e.g., page 13, lines 32 to page 14, line

2; and page 16, lines 25-31). Nevertheless, to expedite prosecution, Applicants have amended claim 1(f), rendering the rejection moot.

d. Applicants have amended claim 4 by deleting the reference to canceled claim 3. Regarding the recitation of “and a pharmaceutically acceptable carrier,” Applicants contend that the antecedent basis for such term is clear to one of skill in the art. Nevertheless, to expedite prosecution, Applicants have amended claim 4 to clarify the subject matter, rendering the rejection moot.

e. Regarding the recitation of “component” in claims 1 and 4, Applicants have removed such recitation from claim 1 and have amended claim 4 to more particularly define the term “component” as “a product of disruption of a whole cell.” In addition, new claim 33 has been added to define that the product is obtained by sonication. Support for such amendment and new claim 33 is found in the specification, for example at page 9, lines 23-25. In addition, the specification describes procedures for preparing such components (e.g., the paragraph spanning pages 3 and 4) and refers to such components (e.g., page 6, lines 25-27). Furthermore, the specification describes activities of cell surface extracts (e.g., page 14, lines 13-16) and describes inhibitory activities of low and high molecular weight metabolites of the lactobacillus (e.g., page 17, lines 17-30).

f. Regarding the recitation of “a resistant starch” in claim 6, Applicants submit that such recitation is art-recognized. Applicants provide the results of various internet searches and references which demonstrate use of the term “resistant starch” (enclosed herewith as **Exhibit B, Documents: “Claim 6 - web search Resistant Starch”; “Resistant Starch”; “L. fermentum web searches & references”**). The specification also provides an example of a “resistant starch” as being “culture Pro<sup>TM</sup>958, Penfold Australia” (e.g., page 20, lines 25-26). Accordingly, the terminology of “a resistant starch” in the context of the present specification would be readily understood by a skilled artisan.

g. Regarding the recitation of “high amylose starch” in claim 7, Applicants submit that such recitation is art-recognized and thus well understood by a skilled artisan in light of the teachings of the specification. Applicants provide the results of internet searches and references which define

the term "high amylose starch" and which use the terminology in a manner consistent with the present application (enclosed herewith as **Exhibit C**, *Documents: "Claim 7 - web search High Amylose Starch"; "High Amylose Starch"; "L. fermentum web searches & references"*).

In addition, Applicants have amended claim 7 to correct claim dependency, thereby overcoming the rejection for lack of antecedent basis for "high amylose starch."

h. Regarding the recitation of "in the form of ... a food product" in claims 10 and 12-13, Applicants traverse the Examiner's assertion that "it is apparent that the composition [in claim 10] is a food product." Claim 10 depends from claim 4 and is intended to further limit that composition to various particular forms. Those stated forms include "a tablet, capsule, powder, paste, gel, liquid formulation, dietary supplement or food product." One of skill in the art would know that at least some of these forms (e.g., tablet and capsule) would **not** fit within a usual understanding of a "food product." Thus, the recitation of "food product" in claim 10 is clear and proper. Further, the recitation of "food product" in claims 12-13 is also clear and proper. Each of these claims imposes a further limitation on the claim from which it depends.

i. Regarding the improper form of multiple dependency in claims 4 and 8-15, Applicants have amended claims 4 and 8-10 to obviate the rejection.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw all rejections under 35 U.S.C. § 112, second paragraph.

Claim Rejections under 35 U.S.C. § 102(b) or § 103(a)

Claims 1-2, 4-5, 8-10, 12, and 14 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by, or in the alternative, under 35 USC 103(a) as allegedly obvious over Heinemann et al. (FEMS Microbiology Letters, 2000, vol. 190). Applicants traverse these rejections to the extent it is maintained over the claims as amended.

Solely to expedite prosecution, Applicants have amended independent claim 1 to include the limitation of claim 2 (the specific *L. fermentum* strain VRI003 described in the Examples in the specification and deposited under the accession no. NM02/31074 in accordance with the Budapest

Treaty). Applicants submit that the amendments are made merely to expedite allowance of claims directed to most commercially relevant embodiments of the present invention. Applicants reserve the right to pursue claims of similar or differing scope in the future.

The standard for anticipating a claim is clearly outlined in MPEP 2131, and this standard is further supported by the Courts. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1978).

Applicants contend that Heinemann et al. fail to satisfy this criteria for anticipating the present invention. Although Heinemann et al. describe a strain of *Lactobacillus fermentum* RC-14, Heinemann et al. do **not** explicitly teach a biologically pure culture of a *Lactobacillus fermentum* variant VRI 003 (accession no. NM02/31074) having the characteristics as recited in claim 1.

The Examiner asserts that "even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the difference between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is **likely to inherently** possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103." (see Office Action, page 7, lines 7-13, emphasis added).

Applicants respectfully disagree. According to MPEP 2112, "[T]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." Further, one court observed that an inherency rejection is valid only if the result "must" occur. See *Continental Can Company v. Monsanto*, 984 F.2d 1264 (Fed. Cir. 1991). This states, "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *Id.* at 1269.

Here, the strain of *Lactobacillus fermentum* RC-14 in Heinemann et al. is described therein as “an isolate from the urogenital tract of a healthy woman” (see page 177). In contrast, the presently claimed strain was isolated from the gastrointestinal tract of a healthy human individual. The Examiner seems to consider this to be the same as, or to render obvious, the presently claimed strain because “it similarly inhibits pathogens.” Even if there is a chance that Heinemann's strain **may** be similar to the claimed strain, one of skill in the art would know that there is no guarantee that the claimed strain will be taught in Heinemann et al. due to the distinct sources of these strains.

Accordingly, Heinemann et al. fail to meet the limitations of independent claim 1, and thus fail to anticipate the claimed subject matter. For the same reasons, all claims that depend from claim 1 are not anticipated by Heinemann et al.

Applicants further submit that none of the other cited references bridge the gap between Heinemann et al. and the claimed invention (e.g., a *Lactobacillus fermentum* variant VRI 003 (accession no. NM02/31074) having the characteristics as recited in claim 1). Accordingly, all claims are not rendered obvious by Heinemann et al.

Claim Rejections under 35 U.S.C. § 102(b) or § 103(a)

Claims 1-2, 4-5, 8-10, 12, and 14 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by, or in the alternative, under 35 USC § 103(a) as allegedly obvious over Plant et al. (Clinical and Diagnostic Laboratory Immunology, Mar. 2001, vol. 8, pages 320-324). Applicants traverse these rejections to the extent it is maintained over the claims as amended.

Applicants contend that Plant et al. fail to satisfy this criteria for anticipating the present invention. Although Plant et al. describe a strain of *Lactobacillus fermentum*, Plant et al. do **not** explicitly teach a biologically pure culture of a *Lactobacillus fermentum* variant VRI 003 (accession no. NM02/31074) having the characteristics as recited in claim 1.

Applicants further submit that Plant et al. do not inherently teach the claimed strain of *Lactobacillus fermentum*. Plant et al. describe the strain *Lactobacillus fermentum* KLD. The Examiner considers this to be the same as, or to render obvious, the presently claimed strain because

it “adheres to Peyer’s Patches.” Applicants note that inventor Patricia Conway is a co-author of Plant et al. Applicants enclose a copy of a Genetic Fingerprinting Report which compares various *L. fermentum* strains (**Exhibit D**). The fingerprinting analysis conducted and described in the Report demonstrates a discernable difference between the KLD strain described in Plant et al. and the claimed strain (see e.g., page 9, Figure 3). As such, one of skill in the art would know that there is no possibility or guarantee that the claimed strain will be taught in Plant et al.

Accordingly, Plant et al. fail to meet the limitations of independent claim 1, and thus fail to anticipate the claimed subject matter. For the same reasons, all claims that depend from claim 1 are not anticipated by Plant et al.

Applicants further submit that none of the other cited references bridge the gap between Plant et al. and the claimed invention (e.g., a *Lactobacillus fermentum* variant VRI 003 (accession no. NM02/31074) having the characteristics as recited in claim 1). Accordingly, all claims are not rendered obvious by Plant et al.

Claim Rejections under 35 U.S.C. § 102(b) or § 103(a)

Claims 1-2, 4-5, 8-10, 12, and 14 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by, or in the alternative, under 35 USC 103(a) as allegedly obvious over Blomberg et al. (Applied and Environmental Microbiology, 1993, vol. 59(1), pages 34-39). Applicants traverse these rejections to the extent it is maintained over the claims as amended.

Applicants contend that Blomberg et al. fail to satisfy this criteria for anticipating the present invention. Although Blomberg et al. describe a strain of *Lactobacillus fermentum* of porcine origin, Blomberg et al. do **not** explicitly teach a biologically pure culture of a *Lactobacillus fermentum* variant VRI 003 (accession no. NM02/31074) having the characteristics as recited in claim 1.

Applicants further submit that Blomberg et al. do not inherently teach the claimed strain of *Lactobacillus fermentum*. Blomberg et al. describe several strains of *Lactobacillus* of porcine origin, the main focus of the document being a *Lactobacillus fermentum* 104R isolated from porcine gastric squamous epithelium (see page 34). The Examiner considers this to be the same as, or to

render obvious the presently claimed strain because “it has antimicrobial effects”. Applicants note that inventor Patricia Conway is a co-author of Blomberg et al. The particular strain described in Blomberg et al. was isolated from porcine gastric squamous epithelium. By contrast, the claimed VRI 003 was an isolate derived from a human faecal sample. One of skill in the art would know that there is no guarantee that the claimed strain will be taught in Blomberg et al., given the distinct sources of these strains. Furthermore, it would not necessarily be obvious, contrary to the Examiner's assertion, that such a strain as disclosed in Blomberg et al. would be suitable for inclusion in a “food product”, especially one to be made available to humans as a probiotic, in view of the fact that the strain of the prior art was isolated from a pig.

Accordingly, Blomberg et al. fail to meet the limitations of independent claim 1, and thus fail to anticipate the claimed subject matter. For the same reasons, all claims that depend from claim 1 are not anticipated by Blomberg et al.

Applicants further submit that none of the other cited references bridge the gap between Blomberg et al. and the claimed invention (e.g., a *Lactobacillus fermentum* variant VRI 003 (accession no. NM02/31074) having the characteristics as recited in claim 1). Accordingly, all claims are not rendered obvious by Blomberg et al.

#### Claim Rejections under 35 U.S.C. § 103(a)

Claims 1-2 and 4-15 are rejected under 35 USC § 103(a) as allegedly unpatentable over Heinemann et al. taken with Mikelsaar et al., and Paul et al. Applicants traverse these rejections to the extent it is maintained over the claims as amended.

As described above, Heinemann et al. do not teach, expressly or inherently, the limitations of independent claim 1 (e.g., a *Lactobacillus fermentum* variant VRI 003 (accession no. NM02/31074) having the characteristics as recited in claim 1). None of the other cited references bridge the gap between Heinemann et al. and the claimed invention. In particular, Mikelsaar et al. describe a strain of *Lactobacillus fermentum* ME-3 which is therein described as being isolated from a faecal sample of a healthy child (see page 4). The Examiner considers this to be the same as, or to render obvious, the presently claimed strain because “it similarly inhibits pathogens and triggers



immune modulation through anti-oxidative effects”. Mikelsaar et al. state that the strain *L. fermentum ME-3* is resistant to several antibiotics, namely metronidazole, ofloxacin, aztreonam, cefoxitin, and TMP-SMX (see pages 7-8). By contrast, the antibiotic resistance profile of the claimed VRI 003 deposit strain differs from that of the strain cited in Mikelsaar et al. (see **Exhibit E**) (see e.g., page 5, Table 2).

Further, according to the Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 In View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* (Federal Register Vol. 72, No. 195 at pages 57,526-57,535) (effective October 10, 2007) (“the Guidelines”), a § 103 claim rejection based on a purported teaching, suggestion or motivation to combine prior art references to arrive at the claimed invention must support a conclusion of obviousness by including: (1) a finding that there was some teaching, suggestion or motivation to modify or combine the cited references; (2) a finding that there was a reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary in view of the specific facts.

As stated by the Supreme Court in *KSR International Co. v. Teleflex Inc.* (550 U.S. \_\_\_, 82 U.S.P.Q.2d 1385 (2007)) (“*KSR*”), the framework for analyzing obviousness under § 103 remains that which was stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) (“*Graham*”) and includes the familiar *Graham* factor analysis referred to in the Guidelines above. In particular, the Supreme Court stated in *KSR*:

“Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. **To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) (‘[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness’)**” (emphasis added).

Applicants submit that the Office Action has not satisfied the requirement of establishing a *prima facie* case of obviousness by explicitly stating articulated reasoning for combining the cited references, as is required by case law. The cited references, singly or in combination, do not provide sufficient basis for the obviousness rejection. Assuming the cited references could be properly combined, the combination still fails to provide any motivation to make the strain VRI 003 (accession no. NM02/31074) as recited in claim 1.

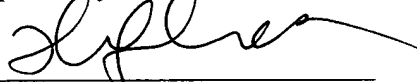
In sum, the requirements for establishing a *prima facie* case of obviousness have not been satisfied. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

### CONCLUSION

This response is accompanied by a request for a three-month extension of time and appropriate fees. If an additional fee is due, please charge our Deposit Account No. 18-1945, under Order No. **BSWV-P01-008** from which the undersigned is authorized to draw. In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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